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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,927	03/16/2001	Eugene Medlock	01017/36917A	7150

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MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER
CHICAGO, IL 60606-6357

EXAMINER	
ANDRES, JANET L	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/17/2002 15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/810,927	MEDLOCK ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) *13,16-58,62-73 and 76-89* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14,15,59-61,74 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I, polynucleotides in Paper No. 14 is acknowledged. The traversal is on the ground(s) that Groups I and II, polynucleotides and polypeptides, are related, that the polypeptide of claim 13 is an inherent product of claim 12, and that the searches would employ the same or similar terms and techniques. This is not found persuasive because the polynucleotides and polypeptides are, as stated in the office action of paper no. 13, unrelated in structure and function. Searches of the two groups require entirely different searches of different databases. Thus, since the searches are different, and the inventions have a different status in the art, as evidenced by their different classification, the requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

2. Applicant's priority claim to 09/723232, 60/189,923, 60/204208, 60/266159, and 60/213125 is acknowledged. The Examiner notes, however, that on p. 1, line 12 of the specification, provisional application 60/266159 is listed as claiming priority to another provisional. Such a claim is improper; see MPEP §201(b)(7).

Information Disclosure Statement

3. Applicant's information disclosure statement filed 15 February 2002 has been considered except for the textbook, C1. The textbook was not provided nor were the relevant pages indicated. The information disclosure statement filed 21 March 2002 has not been considered because it is not present in the file and cannot be located. It will be considered if re-submitted.

Drawings

4. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

5. The abstract of the disclosure is objected to because the first sentence is incomplete. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: There are blank spaces on p. 8, lines 29 and 30 p. 151, lines 5 and 6, p. 152, line 8, and p. 154, line 22.

Appropriate correction is required.

The use of the trademark BLUESCRIPT™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-12, 14, 15, 59-61, 74, and 75 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/14240, Shi et al, 25 March 1999.

WO 99/14240 teaches a polynucleotide that encodes an IL-17 receptor-like protein (Figure 1). Nucleotides 7-312 of this polynucleotide are identical to residues 47-352 of instant SEQ ID NO: 4 and nucleotides 364-1799 are identical to residues 578-2015 of instant SEQ ID NO: 4 except for three mismatches (see sequence alignment appended to the document). Thus WO 99/14240 teaches an IL-17 receptor-like polynucleotide that would hybridize to the complement of SEQ ID NO: 4 under stringent or moderately stringent conditions, as specified in

claim 1, comprises a fragment of SEQ ID NO: 4 of at least 16 nucleotides as specified in claim 2, encodes a polypeptide having at least one amino acid deletion relative to that encoded by SEQ ID NO: 4 as specified in claim 3, and is 76% identical to SEQ ID NO: 4, and is thus encompassed by claims 2 and 15. Vectors and host cells as claimed in claims 4-12, 14, and 61 are taught on p. 6, lines 8-16, p. 38, lines 26-28, p. 39, lines 1-2, and p. 45, line 8 – p. 46, line 23. Pharmaceutically compatible compositions as claimed in claim 59 and 60 are taught on p. 87, lines 10 and 11. Polynucleotides with a detectable label, as claimed in claims 74 and 75, are taught on p. 103, lines 26-27.

8. Claims 1-12, 14, 15, 59-61, 74, and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0102639, Shaughnessy, which claims priority to 4 February 2000.

US 2002/0102639 teaches a polynucleotide that encodes an IL-17 receptor-like protein (SEQ ID NO: 1; see abstract for its identification as a IL-17 receptor-like molecule). Nucleotides 1-308 of this polynucleotide are identical to residues 45-352 of instant SEQ ID NO: 4 except for one mismatch and nucleotides 360-1794 are identical to residues 578-2012 of instant SEQ ID NO: 4 except for two mismatches (see sequence alignment appended to the document). Thus US 2002/0102639 teaches an IL-17 receptor-like polynucleotide that would hybridize to the complement of SEQ ID NO: 4 under stringent or moderately stringent conditions, as specified in claim 1, comprises a fragment of SEQ ID NO: 4 of at least 16 nucleotides as specified in claim 2, encodes a polypeptide having at least one amino acid deletion relative to that encoded by SEQ ID NO: 4 as specified in claim 3, and is 77% identical to SEQ ID NO: 4, and is thus encompassed by claims 2 and 15. Vectors and host cells as claimed in claims 4-12, 14, and 61 are taught on p. 3, paragraphs 34 and 35, p. 4, paragraphs 37, 38, 41, and 42.

Pharmaceutically compatible compositions as claimed in claim 59 and 60 are inherent in the therapeutic uses contemplated by US 2002/0102639, for example on p. 13, paragraph 125. Polynucleotides with a detectable label, as claimed in claims 74 and 75, are taught on p. 6, paragraphs 48 and 49.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 2, 4-12, 14, 15, 59-61, 74, and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims encompass allelic variants of the disclosed sequence. However, such variants are not described in the specification. Allelic variants are polynucleotides that exist in nature and have particular sequences. Because these particular sequences are not set forth in the specification, one of skill in the art would not reasonably conclude that Applicant was in possession of them at the time of filing.

11. Claims 7-9, 12, and 14 are additionally rejected as containing subject matter not described in the specification because they encompass sequences comprising fragments, but require no function or other identifying characteristics. These claims are thus drawn to a genus of polynucleotides that includes sequences of any length, comprising any fragments. and means of expressing them. Applicant has described the polynucleotide sequences of SEQ ID Nos 1, 4,

and 6. However, the claims encompass polynucleotides that vary substantially in length and also in composition, with no requirement for any particular structural feature or function. The instant disclosure of these three nucleic acids thus does not adequately describe the scope of the claimed genus. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly&Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification discloses three isolated cDNA sequences and the translated amino acid sequences. There is no description of the required structural and functional features of the claimed molecules, or of the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what variations could be tolerated without altering them. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus of sequences comprising fragments of the disclosed sequences.

12. Claims 7-9, 12, and 14 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides of SEQ ID Nos: 1, 4 and 6, does not reasonably provide enablement for polynucleotides of sequences comprising fragments of these sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Applicant has described the polynucleotides of SEQ ID Nos: 1, 4, and 6. However, applicant has not described the characteristics of these nucleic acid sequences so that one of skill in the art could predictably identify other sequences encoding IL-17 receptor-like molecules. Applicant has not described the properties or characteristics of the sequences that are required to encode a functional protein or any other essential characteristics of nucleic acids encoding IL-17 receptor-like proteins . Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result in IL-17 receptor-like function, in order to practice the invention commensurate with the scope of the claims without undue experimentation.

13. Claims 74 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to diagnostic reagents. However, Applicant has described no diseases or conditions known to be associated with the encoded protein for which its presence or absence would be diagnostic. What is set forth in the specification on pages 100-103 is a general list of diseases. There is no objective evidence, no working examples, and no other direction provided by which one of skill in the art could determine which of these conditions, if any, the polynucleotide could actually be used to diagnose; all that is presented is a number of possibilities. This is not adequate guidance as to the nature of the diseases that may be diagnosed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Further, the prior art fails to provide compensatory guidance; neither WO 99/14240 nor 2002/0102639 describe any diseases known to be associated with the encoded protein. Thus, without further guidance, one of skill in the art could not predictably identify which diseases the polynucleotide could be used to diagnose, and it would therefore require undue experimentation for the skilled artisan to use the polynucleotide for this purpose.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-12, 14, 15, 59-61, 74, and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claims 1-6, 10-12, 14, 15, and 59-61 are indefinite in the recitation of "has an activity of". There is no particular activity or set of activities defined for the encoded protein in the specification. Thus one of skill in the art would not know what activities, and thus what molecules, Applicant intended the claims to encompass.

17. Claims 1-6, 10-12, 14, 15, and 59-61 are also indefinite in the recitation of "moderately" or "highly" stringent conditions. There is no definition of either of these conditions in the specification; only examples are provided on pages 34-36. Thus one of skill in the art would not know what activities, and thus what molecules, Applicant intended the claims to encompass.

18. Claims 2, 4-6, 10-12, 14, 15, and 59-61 are indefinite because the limitations of 2(d) are not clear. It is unclear as to whether the claimed molecules comprise fragments of the disclosed sequences, or only of the molecules encompassed by (a)-(c), and whether the functional limitations of (a)-(c) are included in (d).

19. Claims 7 –9, 12, and 14 are indefinite in the recitation of "a fragment thereof", since it is not clear from which sequences the fragment may be derived. In addition, the claims do not require that the cell be transfected with an IL-17 receptor-like polynucleotide.

20. Claims 74 and 75 are indefinite in the recitation of "variant or homolog". There is no definition in the specification of such variants or homologs, and no other limitation in the claims by which they could be identified. The description of polypeptide variants on p. 25 includes no limitations as to the degree of variation that is encompassed, or any other identifying characteristics of such variants. There is no description of homologs. Thus one of skill in the art would not be able to determine what molecules were considered to be variants or homologs, and what molecules would not be, and would not know what molecules were encompassed by these limitations. In addition, these claims encompass "spliced variants". While the meaning of "splice variant" is known in the art, a "spliced variant" could potentially encompass any variant, which is itself indefinite, attached to anything else. One of skill in the art thus could not determine what molecules were encompassed.

Double Patenting

21. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

22. Claims 1-4, 14, 15, 59-61, 74, and 75 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 10, 11, 47-49, 59, and 60, respectively, of copending Application No. 09/723232. The claims are identical. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 5-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-8 and 10 of copending Application No. 09/732232. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Instant claims 5 and 10-12 differ from claims 5-8 of 09/723232 only in they do not specifically require that the polynucleotides be present in a vector, which would be necessary for expression. Instant claim 6 is drawn to a cell that is essential for the method of claim 10 of 09/732232. Instant claims 7-9 differ from claim 5 of 09/732232 only in that they more specifically encompass art-standard components of the vector.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly

signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner

December 13, 2002